

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

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| <b>IN RE: ETHICON, INC. PELVIC REPAIR<br/>SYSTEM PRODUCTS LIABILITY<br/>LITIGATION</b> | )<br>)<br>)<br>)<br>)<br>) | <b>Master File No. 2:12-MD-02327<br/>MDL No. 2327<br/><br/>JOSEPH R. GOODWIN<br/>U.S. DISTRICT JUDGE</b> |
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**THIS DOCUMENT RELATES TO:** )  
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**WAVE 3 CASES LISTED IN EXHIBIT 1** )  
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**PLAINTIFFS' RESPONSE AND OPPOSITION TO DEFENDANTS' MOTION TO  
EXCLUDE CERTAIN OPINIONS OF ABBAS SHOBEIRI, M.D.**

Plaintiffs, identified in Ex. 1 attached hereto, submit their response and opposition to Defendants' Supplemental Motion to Exclude Certain Opinions of Abbas Shobeiri, M.D.

**INTRODUCTION**

Dr. Shobeiri is a professor of Obstetrics and Gynecology at George Washington University and Virginia Commonwealth University. He is a practicing surgeon and is board certified in Obstetrics/Gynecology and Female Pelvic Medicine and Reconstructive Surgery. His qualifications are set forth more completely in the initial briefing in this matter and do not need full repeating here.

On August 30, 2016, this Court issued a Memorandum Opinion and Order on Ethicon's initial *Daubert* Motion against Dr. Shobeiri.<sup>1</sup> In that decision, the Court denied Ethicon's motion to exclude Dr. Shobeiri's opinion that the TVT-O and Prolift are defectively designed because

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<sup>1</sup> Ex 1.

polypropylene mesh can shrink, contract, deform, coil, rope, and fray. Despite this, Ethicon now comes before the Court asking it to reverse itself concerning the admissibility of these design defect opinions. Ethicon does not base its motion on any new evidence, deposition, expert report, or circumstances with respect to Dr. Shobeiri's opinions; it simply wants this Court to rule a different way in Wave 3 than it did based in Wave 1 based on the very same record. *See id.* at 3 ("Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.") (emphasis added).

The newly filed brief essentially asks this Court to exclude all of Dr. Shobeiri's general opinions that the TVT-O device can cause pain and dyspareunia in women.<sup>2</sup> Ethicon seems to believe that because other surgeries and conditions may cause similar complaints of pain and dyspareunia in women, Dr. Shobeiri should not be permitted to opine that the TVT-O device can also cause those complaints. *See* Ethicon Br. at 2 (arguing that Dr. Shobeiri's opinions on design defect in general should be excluded because "his deposition testimony . . . demonstrates that the risks that Dr. Shobeiri connects with the TVT-O product as 'more likely than not' to cause injury in fact occur in the *absence* of the TVT-O.") However, this argument is flawed in two distinct ways: *first*, the argument misrepresents and misconstrues Dr. Shobeiri's opinions on mesh related injuries; and (2) the fact that other surgeries can cause complications in women is irrelevant to a *Daubert* challenge.

*First*, Ethicon's entire argument is premised on the false notion that Dr. Shobeiri opined that the injuries caused by mesh are the same as the injuries caused by other medical conditions

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<sup>2</sup> Ex 2.

and surgeries. This is simply a misrepresentation of the clear record in this case. Instead, Dr. Shobeiri repeatedly offered opinions in his report and at his deposition that the design of Ethicon's polypropylene products can cause complications in women that "are unlike those seen with other pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment." Ex. 2 at 5. *See also* Ex 2 at 15 ("These complications are very different from those seen in native tissue pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment."). Thus, while Dr. Shobeiri testified that other surgeries and conditions may cause dyspareunia, scarring and nerve damage, he also testified that these complications in TVT-O patients can be more severe, more permanent and more frequent. *See Ex. 3* Feb 27, 2016 Deposition at 81:22-82:15 ("Mesh complications are unlike those seen with the other pelvic surgery in terms of onset, frequency, severity, character, responsiveness to treatment. . . . So in terms of TVT-O, the mesh arms are going through a space that generally obstetrician/gynecologists were not familiar with. So the kind of problems that occurred in terms of dealing with those problems, really understanding the frequency, the severity, the character of them, how to respond to, are very difficult. . . . So these are very unique type of problems."). *See also id.* at 85:10-20; 129:17-130:17 (bladder infections more common with TVT-O than other kinds of mesh); 131:11-15 (Q. But in your opinion, urinary tract infections or bladder infections would be more common with TVT-O than with TVT mesh? A. Yeah. The thing is that their mechanisms can be different, too.") As he testified explicitly in his deposition, while the type of complications can occur with other vaginal surgeries, "they're just very infrequent." *Id.* at 124:11-18.<sup>3</sup> Thus, Ethicon's entire argument is premised on the fallacy that the complications from mesh are the same as the complications from other conditions and surgeries; therefore, its entire argument must fail.

*Second*, even if Dr. Shobeiri did opine that the complications associated with mesh are the same as the complications associated with other conditions and surgeries, *i.e.* that they are not “unique” to the TVT-O device, the motion should still be denied. It is irrelevant to the claims in general whether the injuries are signature or unique to the TVT-O device and there is absolutely no requirement under *Daubert* that experts be permitted to opine solely on signature or unique injuries caused by a drug or medical device. Provided that the expert can provide a reasonable basis for the opinions in his report, the opinions are deemed reliable and should be admitted. *See* Rule 702(b)(d) (a qualified expert may offer expert testimony that is based on “sufficient facts or data” reliably applied to the case.). The fact that there may be other conditions that cause the same or similar injuries goes, at best, to the weight of the opinions and not their admissibility. *See Hall v. Boston Scientific Corp.*, C.A. No. 2:12-cv-08186, 2015 WL 868907, at \*23 (S.D. W. Va. Feb. 27, 2015) (admitting medical expert’s general opinions and holding that it is not the Court’s place at the *Daubert* stage to decide the “rightness” of an expert’s conclusions; it should focus on whether the expert’s methodology was sound: “Whether Dr. Ostergard correctly interpreted this research has no bearing on the admissibility of his opinions.”).

Finally, Ethicon’s cannot credibly question the basis for Dr. Shobeiri’s opinions on the increased frequency and severity of complications associated with the TVT-O. As this Court noted in its Order on Ethicon’s first motion to exclude Dr. Shobeiri’s design defect testimony,

Ethicon challenges the reliability of Dr. Shobeiri’s defective design testimony because he “cites no scientific studies.” To the contrary, a review of Dr. Shobeiri’s expert report shows he cites to numerous studies in support of his opinions. Accordingly, I find Ethicon’s argument without merit and DENY its Motion on this matter.

Ex. 1 at 7. The basis for this testimony is the exact same as it was when first challenged by Ethicon and this Court has been presented with no new reason to change its prior ruling.<sup>4</sup>

## **I. CONCLUSION**

For the reasons of the foregoing, Dr. Shobeiri's general opinions are reliable and should be admitted in full.

Date: October 11, 2016

Respectfully submitted,

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<sup>4</sup> It is surprising that Ethicon would challenge Dr. Shobeiri's opinions on these grounds when it is consistent with the position that their own experts have taken with respect to the TVT-O device. For example, Dr. Lowman, one of Ethicon's experts, testified at her deposition that she will not use the TVT-O device because its sister product, the TVT device, "has a lower risk of pelvic pain and groin pain and has a higher success rate . . . than transobturator slings." Deposition of Dr. Lowman, pp23 line9-p.24 line18 (objections excluded for readability) (excerpt included as Ex 4).

**CERTIFICATE OF SERVICE**

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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